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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,423	10/22/2003	Joseph Oncal	APROG.0101	6169
22858 7590 02/20/2007 CARSTENS & CAHOON, LLP P O BOX 802334 DALLAS, TX 75380			EXAMINER KRISHNAN, GANAPATHY	
			ART UNIT	PAPER NUMBER
			1623	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/20/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/691,423	ONEAL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ganapathy Krishnan	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The amendment filed 12/5/2006 has been received, entered and carefully considered.

The following information provided in the amendment affects the instant application:

Remarks drawn to rejections under 35 USC 102 and 103

Exhibits A-C

Claims 1-17 are pending in the case.

The following new art rejections are made of record.

#### ***Claim Rejections - 35 USC § 102***

The rejection of Claims 1-10 and 15-16 under 35 U.S.C. 102(b) as being anticipated by Wright (Alternative Medicine, Townsend Letter for Doctors & Patients, July, 1999, pages 2-3) has been withdrawn in view of applicants' arguments.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright (Alternative Medicine, Townsend Letter for Doctors & Patients, July, 1999, page 96 and 98), Kumar et al (Indian Journal of Medical Research, 1982, 76 (suppl.), pages 46-53; see English

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abstract) newly cited, Carella et al (WO 97/29763) and Iwahi et al (J. Med. Microbiol., 1982, 15(3), 303-316) of record.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Wright teaches the use of D-Mannose for the treatment of urinary tract infections (page 96, left column, 4<sup>th</sup> paragraph; middle column, 3<sup>rd</sup> and 4<sup>th</sup> paragraphs; right column, first full paragraph). The dosage is one teaspoon, approximately 1-2.5 g, in the form of a powder dissolved in water, every three to four hours (page 96 right column, last paragraph and page 98, left column, first paragraph). However, Wright does not teach the treatment of urinary tract infections by administration of D-mannose powder directly or in combination with other extracts and compositions comprising D-Mannose and the extracts as instantly claimed.

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Kumar et al drawn to crataeva nurvala, teach that it is highly reputed for its therapeutic value in the treatment of urinary tract infections (see English abstract). However, Kumar et al do not suggest the combination of D-mannose and crataeva nurvala for the treatment of urinary tract infections. In addition to urinary tract infections other urinary disorders can also be treated by using crataeva nurvala.

Carella et al teach the use of D-mannose in a composition for the promotion of a healthy environment in urogenital tracts and for treating urogenital disorders (page 2, lines 7-10 and 16-17; page 5, lines 15-16). Plant extracts (interpreted as herbs that affect urinary tract, as instantly claimed in claim 5) are also included in the composition (page 8, lines 23-27). The compositions can be administered as tablets, capsules (page 10, lines 7-10) and can contain 5 to about 75% per unit dose (page 6, lines 22-25). According to Carella additional ingredients and dosages can be readily ascertained using routine experimentation (page 14, lines 32-35). This means that the art recognizes that the dosages can be varied or frequency of administration adjusted till symptoms subside.

Iwahi et al teach that d-mannose is potent in inhibiting viral adhesion to the urinary tract (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer d-mannose containing the herbal extracts as instantly claimed, to treat urinary tract infection since the use of mannose and the said herbal extracts like crataeva nurvala for the said treatment is seen to be taught in the prior art. One of ordinary skill in the art would be motivated to use d-mannose and pollen extract and extracts of crataeva nurvala and willow bark as the active agents since d-mannose is potent in preventing viral adhesions to the urinary

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tract as taught by Iwahi et al and the extracts of pollen, crataeva nurvala and willow bark have additional benefits as taught by Kumar.

It has been held that it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition that is to be used for the very same purpose. The idea of combining them flows logically from their having been taught individually in the prior art. See *In re Kerkhoven*, 205 USPQ 1069, CCPA 1980.

It is well within the purview of one of ordinary skill in the art to include other herbal extracts known for treatment of urinary tract infections and also adjust the administration dosage and the amounts in the compositions as instantly claimed in order to get the maximum beneficial effects of the active agents.

### ***Response to Applicants Arguments***

Applicants' have traversed the rejections advanced in the previous office action by pointing out that the Wright article has a copyright of 2004 and attributes information to the assignee of the instant application. The dosage mentioned in the reference used is not disclosed in the article but is rather an advertisement (U-TRACT #869 dosage information) with a copyright of 2004 and hence the use of the reference is improper in the 102 and 103 rejections. Applicants have also submitted Exhibits A-C that has been reviewed.

The 35 USC 102 and 103 rejections advanced in the previous office action has been withdrawn base on the arguments of the applicants and rejections under 35 USC 103(a) as above is made of record.

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*Conclusion*

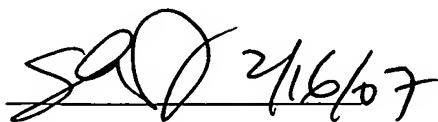
Claims 1-17 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GK



Shaojia Jiang  
Supervisory Patent Examiner  
Art Unit 1623